IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (GBW) **DEMAND FOR JURY TRIAL**
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff/Counter Defendants.	[redacted]

PLAINTIFF'S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT NO. 2 REGARDING INFRINGEMENT OF CERTAIN NS PATENTS

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I. THE RELEVANT NS PATENTS

1. Nippon Shinyaku Co., Ltd. ("NS") holds the exclusive assertion rights with respect to US Patent No. 10,385,092 (the "'092 Patent"), US Patent No. 10,407,461 (the "'461 Patent"), US Patent No. 10,487,106 (the "'106 Patent"), US Patent No. 10,647,741 (the "'741 Patent") and US Patent No. 10,662,217 (the "'217 Patent") (collectively, the "At-Issue NS Patents"). *See* NS's Second Amended Complaint (D.I. 86), ¶ 46; Memorandum on the Pursuit of Litigation for Co-Owned Patents (D.I. 39-5).

2. Claims 1-3 of the '092 Patent, claims 1-2 of the '461 Patent, and claims 1-2 of the '106 Patent (collectively, the "NS Product Claims") are each directed to a phosphorodiamidate morpholino oligomer ("PMO"). '092 Patent (D.I. 2-3); '461 Patent (D.I. 2-4); '106 Patent (D.I. 2-5); Ex. 4 (Esau Opening) ¶¶ 29-33.

3. Claims 1-12 of the '741 Patent and claims 1-4 of the '217 Patent (collectively, the "NS Method of Use Claims") are directed to methods of using a PMO. '741 Patent (D.I. 2-6); '217 Patent (D.I. 2-7); Ex. 4 (Esau Opening) ¶¶ 30, 34-35.

II. SAREPTA'S ACCUSED PRODUCT

4. Sarepta markets, sells, and/or offers to sell a product called Vyondys 53® in the United States, which contains an active ingredient called golodirsen. Sarepta's Second Amended Answer (D.I. 328), ¶¶ 3, 11, 23; Ex. 4 (Esau Opening) ¶¶ 142-149.

5. Golodirsen is an antisense oligomer of the PMO subclass. Sarepta's Second Amended Answer (D.I. 324), ¶ 3; Ex. 4 (Esau Opening) ¶¶ 52-54; Ex. 32 (Vyondys 53® Highlights of Prescribing Information (SRPT-VYDS-0006978)) § 11.

6. [redacted]

[redacted]

7. [redacted]

8. [redacted]

9. [redacted]

10. [redacted]

[redacted]

III. THE MANUFACTURE OF GOLODIRSEN

11. [redacted]

[redacted]

12. [redacted]

[redacted]

13. [redacted].

IV. THE USE OF GOLODIRSEN

14. Vyondys 53® (golodirsen) is approved by the FDA for a single indication—"the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the *DMD* gene that is amenable to exon 53 skipping." Ex. 32 (Vyondys 53® Highlights of Prescribing Information (SRPT-VYDS-0006978)) § 1; *see also* Ex. 4 (Esau Opening) ¶ 318.

15. Sarepta provides medical professionals with detailed instructions as to how to administer Vyondys 53® (golodirsen) to patients. Ex. 32 (Vyondys 53® Highlights of Prescribing Information (SRPT-VYDS-0006978)) § 2; *see also* Ex. 4 (Esau Opening) ¶ 319.

16. The only approved method for administering Vyondys 53® (golodirsen) is by using intravenous infusion. Ex. 32 (Vyondys 53® Highlights of Prescribing Information (SRPT-VYDS-0006978)) § 2.4; *see also* Ex. 4 (Esau Opening) ¶ 319.

V. SAREPTA'S KNOWLEDGE OF THE NS PATENTS

17. Each of the At-Issue NS Patents are a child of a PCT application that was filed on August 31, 2011 and issued as US Patent No. 9,079,934 (the "Parent PCT Application"). '092 Patent (D.I. 2-3); '461 Patent (D.I. 2-4); '106 Patent (D.I. 2-5); '741 Patent (D.I. 2-6); '217 Patent (D.I. 2-7); Ex. 4 (Esau Opening) ¶¶ 174, 305.

18. [redacted] Ex. 18 ([redacted] Dep.) at [redacted]; Ex. 4 (Esau Opening) ¶¶ 175, 306.

19. [redacted] Ex. 18 ([redacted] Dep.) at [redacted]. Ex. 4 (Esau Opening) ¶¶ 176, 307.

20. Sarepta filed petitions for *inter parties* review (the "IPRs") with respect to each of the At-Issue NS Patents with the Patent Trial and Appeal Board ("PTAB") of the United States

Patent and Trademark Office ("USPTO") on June 21, 2021. Sarepta's Second Amended Answer (D.I. 328), ¶¶ 1, 66.

VI. SAREPTA'S INFRINGEMENT OF THE NS PATENTS

21. Golodirsen meets each and every limitation of the NS Product Claims. Ex. 4 (Esau Opening) ¶¶ 47-141; Ex. 13 (Dowdy Dep.) [redacted].

22. Sarepta has not identified any limitation of the NS Product Claims that is not met by golodirsen. Ex. 26 (Non-Infringement Contentions at Exhibits A-2 to A-4); Ex. 2 (Dowdy Rebuttal) ¶¶ 475-491; *see also* Ex. 13 (Dowdy Dep.) [redacted].

23. Sarepta has directly infringed and will continue to directly infringe the NS Product Claims under 35 U.S.C. § 271(a) by selling Vyondys 53® (golodirsen), offering Vyondys 53® (golodirsen) for sale, and/or directing and controlling the manufacture of Vyondys 53® (golodirsen). Ex. 4 (Esau Opening) ¶¶ 142-159.

24. Sarepta has not identified any contention that it did/does not infringe the NS Product Claims by selling Vyondys 53® (golodirsen), offering Vyondys 53® (golodirsen) for sale, and/or directing and controlling the manufacture of Vyondys 53® (golodirsen). Ex. 26 (Non-Infringement Contentions) at 4-8 ([redacted]); Ex. 2 (Dowdy Rebuttal) ¶¶ 475-491.

25. Sarepta has indirectly infringed and will continue to indirectly infringe the NS Product Claims under 35 U.S.C. § 271(b) by inducing others to manufacture Vyondys 53® (golodirsen) and/or administer Vyondys 53® (golodirsen). Ex. 4 (Esau Opening) ¶¶ 160-195.

26. Sarepta has indirectly infringed and will continue to indirectly infringe the NS

Product Claims under 35 U.S.C. § 271(c) by contributing to others' use of Vyondys 53® (golodirsen). Ex. 4 (Esau Opening) ¶¶ 196-205.

27. The use of golodirsen meets each and every limitation of the NS Method of Use Claims. Ex. 4 (Esau Opening) ¶¶ 217-294; Ex. 13 (Dowdy Dep.) [redacted].

28. Sarepta has not identified any limitation of the NS Method of Use Claims that is not met by the use of golodirsen. Ex. 26 (Non-Infringement Contentions at Exhibits A-2 to A-4); Ex. 2 (Dowdy Rebuttal) ¶¶ 475-491; *see also* Ex. 13 (Dowdy Dep.) [redacted].

29. Sarepta has indirectly infringed and will continue to indirectly infringe the NS Method of Use Claims under 35 U.S.C. § 271(b) by inducing others to administer Vyondys 53® (golodirsen). Ex. 4 (Esau Opening) ¶¶ 295-323.

30. Sarepta has indirectly infringed and will continue to indirectly infringe the NS Method of Use Claims under 35 U.S.C. § 271(c) by contributing to others' use of Vyondys 53® (golodirsen). Ex. 4 (Esau Opening) ¶¶ 324-333.

31. Sarepta has not identified any contention that it did/does not indirectly infringe the NS Product Claims and NS Method of Use Claims under 35 U.S.C. § 271 (b) and (c). Ex. 26 (Non-Infringement Contentions) at 4-8 ([redacted]); Ex. 2 (Dowdy Rebuttal) ¶¶ 475-491.

32. Sarepta's counsel has stated that "Sarepta is willing to draw its defense of (i) no direct infringement, induced infringement and contributory infringement of [the NS Product Claims], and (ii) no induced and contributory infringement of [the NS Method of Use Claims]." Ex. 37 (Email from Ryan O'Quinn to Amanda Williamson), dated December 6, 2023.